

THE SAN ANTONIO ORTHOPAEDIC GROUP
HopeStar Orthopedic Group, L.L.P.

Albert E. Sanders, M.D.
Surgery of the Spine & Scoliosis

Stephen S. Burkhart, M.D.
Lamar P. Collie, Jr., M.D.
Stephen C. Drukker, M.D.
Frank J. Garcia, M.D.
Gerald Q. Greenfield, Jr., M.D., F.A.C.S.
Adam I. Harris, M.D.
Frank K. Kuwamura III, M.D.
Keith L. Markey, M.D., F.A.C.S.
Sanjay Misra, M.D.
Paul D. Pace, M.D., F.A.C.S.
Uwe R. Pontius, M.D., Ph.D.
Spencer A. Rowland, M.D.
Albert E. Sanders, M.D.
Brad S. Tolin, M.D.
Daniel C. Valdez, M.D.

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Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

RE: Docket #97N-484S

Gentlemen:

John Hinchey, M.D.
Emeritus

Downtown
Metropolitan Prof. Bldg.
1303 McCullough, Suite 135
San Antonio, Texas 78212
(210) 225-5741 Fax (210) 229-9974

Nix Medical Center
414 Navarro, Suite 1407
San Antonio, Texas 78205
(210) 271-7767 Fax (210) 224-4566

Santa Rosa Pavillion
315 N. San Saba, Suite 1100
San Antonio, Texas 78207
(210) 222-2212 Fax (210) 271-3498

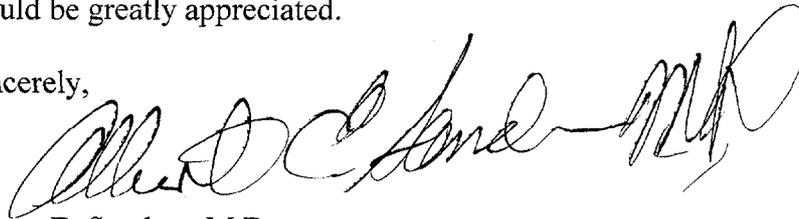
Medical Center
Santa Rosa N.W. Tower I
2829 Babcock Road, Suite 700
San Antonio, Texas 78229
(210) 614-4263 Fax (210) 616-0259

North Central
Stone Oak Medical Building
540 Madison Oak Drive, Suite 620
San Antonio, Texas 78258
(210) 494-2297 Fax (210) 494-5445

Southwest
Southwest Diagnostic Building
88 Briggs Ave., Suite 170
San Antonio, Texas 78224
(210) 922-0808 Fax (210) 924-7880

I take care of patients with spine deformities, both scoliosis and kyphosis, and use a significant amount of bank bone. This is used exclusively in posterior fusions and patients with neuromuscular scoliosis since instrumentation ordinarily includes the pelvis. These patients have a relatively small ilium and with part of the ilium being occupied by the internal fixation, there is not enough available ilium to use as an autologous graft. The complication rate has been very low in these patients, and most have gone on to a solid healing. Allograft bone is also used for anterior grafting when appropriate autologous bone is not available and, again, bone which is under compression ordinarily incorporates quite well. I believe that there is sufficient evidence to support the efficacy and safety of allograft bone and that further FDA pre-market requirements, such as clinical trials, would significantly limit the use of this valuable material in patient care. Reconsideration of the proposed new regulations regarding allograft bone would be greatly appreciated.

Sincerely,

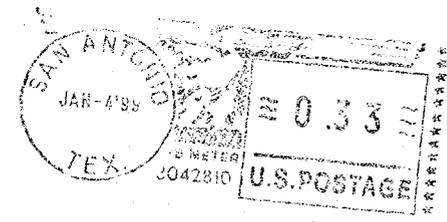


Albert E. Sanders, M.D.
AES/jft

97N 484S

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ALBERT E. SANDERS, M.D., P.A.
ORTHOPEDIC SURGERY
SUITE 1431, NIX PROFESSIONAL BUILDING
414 NAVARRO STREET
SAN ANTONIO, TEXAS 78205



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